EXHIBIT 4

From: Mahar, Kevin [ETHUS]
Sent: Sat, 20 Jun 2009 11:21:52 GMT
To: Mahar, Kevin [ETHUS] <KMahar@ITS.JNJ.com>
Subject: FW: Gynecare Prolift: Global launch plan, budget, Gant chart

Importance: High

From: Walji, Zenobia [ETHUS]
Sent: Friday, September 03, 2004 3:48 PM
To: Berthier, Ophelie [JNJFR]; Bonet, Giselle [ETHUS]
Cc: Bell, Steve [ETHIT]; Mahar, Kevin [ETHUS]
Subject: FW: Gynecare Prolift: Global launch plan, budget, Gant chart
Importance: High
Sensitivity: Confidential

Dear Ophelie & Giselle,

This is an excellent first draft! With a desire to get some comments back to you as quickly as possible, I have not tried to "word-smith" anything, but rather focus on the big things. My comments have been made in red in the attached word document for your review. Overall, Ophelie as per our phone conversation, here are some additional points that I think will require additional thought and time:

1) Basis especially where the US is with GYNEMESH PS 2004 sales and with respect to TRUE acceptors of large pieces of mesh for prolaps repair, we have a lot of work to do. Realistically therefore, especially since Pre-launch monies have been allocated, it is important to have a **section of Pre-launch that focuses on WHAT we will do to build more advocates of GYNEMESH PS** - I mean users of large mesh. **This should be separate from the Pre-launch of D'Art.** In reality we need to have both activities to achieve success. This clarity will also help make sure that we have the solid support before we spend too much on D'Art activity pre-maturely....

2) An obvious question that management will be interested in is **HOW we will MEASURE success** of our pre-launch work? Will we have questionnaires? What if only 60% of preceptors who are exposed to D'Art are willing/convinced to start, do we scale back our plans, do we do something different? **Remember you are selling a concept first and then a product. When/How will you know if the market has accepted the concept and is ready for the product?**

3) While there is some cleaning up to do in the overall market model, I think you need to think about a spreadsheet that has units of GYNEMESH PS sold to date, and also separately the number of users of GYNEMESH PS. From there, you should project out how many doctors you must enroll and prepare during Pre-launch and Launch to achieve your forecast numbers...For example, if we are selling @ 500 units a month in August, how much ramp can we expect by year-end, and what will it look like through each month of 2005 for GYNEMESH and separately one line for D'Art... The combined will tell you what forecast REALISTICALLY the team is prepared to commit to...Laura has apparently told the Board that US and EU combined for 2005 will be $3.1-3.5 MM not including GYNEMESH PS. Before there are too many more numbers flying around, the team should agree and be prepared to defend it.

4) Most of my comments are around Positioning and Claims - its important we have a strong and clear statement here.

5) To keep the document crisp, just as you have done with "Clinical Strategy" , you need a title of Regulatory Strategy, Reimbursement Strategy, Communication Strategy (instead of Launch Materials), Promotional Strategy, Convention Strategy (instead of Exhibition strategy) , Manufacturing Strategy (instead of Product Logistics) Ophelie, also a couple items that are missing:

- **Value Proposition** (Physicians, Patients, Payers, Site of Care)... you have Features and Benefits, but it is not the same (I know that work was started on this between Scott and you...)
- **Reimbursement** - Laurent has collected this info, but not sure how complete it is
- **Assumptions** - I have suggested you include that as part of the Forecast section...

I trust this is a good start...I may think of other things and will advise later. Overall, great job and thanks for the solid progress! I'll be in touch to discuss numbers some more once Giselle is back on Tuesday. Tks

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-----Original Message-----
From: Berthier, Ophelie [JNJFR]
Sent: Friday, September 03, 2004 10:08 AM
To: Bell, Steve [ETHIT]
Cc: Walji, Zenobia [ETHUS]; Bonet, Giselle [ETHUS]
Subject: Gynecare Prolift: Global launch plan, budget, Gant chart
Sensitivity: Confidential

Steve,
As requested for the conf call of Laura with Et Carino on Monday afternoon, you will find enclosed the drafts of:

Gynecare Prolift Launch Plan
The executive summary needs to be finalized. I prefer to wait for a first feedback before.
Objective-Pelvic Floor Strategy needs to be developed but I preferred to focus on the other items.
Competitive landscape: I will probably develop a part on each key competitor and their products later on. As time was running, I put the info I already knew.
Fastener: as few documents are available on fastener and launch should occur later in 2005, I didn't include the fastener in the plan yet.

Gant chart:
We did a chart with several tab: one for marketing tools, market seeding, Prof Ed, Internal training, Clinicals

Budget:
We built the budget out of the 650K$ and we will isolate the EU expenses from the US expenses once we have approval on the spendings. We also included 2005 expenses for Global Launch.

A big thank to Giselle who contributed to the realization of all those documents and made me able to send all those drafts today.
Looking forward for your feedback,

Ophélie

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Gynecare PROLIFT*
Pelvic Floor Repair Systems

Global Launch Plan

Draft 2.0 2th September 2004

Contents

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

1. Executive Summary

The Pelvic Floor platform opportunity worldwide is $300MM. (Here you should include what the clinical unmet need is and why Pelvic Floor Repair is so important – i.e. high reoccurrence rates, no standard procedures, poor/inconsistent clinical outcomes as the procedures today are very surgeon skill dependent. Then explain what the opportunity is and why this strategically important for GYNECARE and why GYNECARE is well-placed to lead the market in (his area) Moreover, sustained leadership in Incontinence requires significant participation in PF market and GYNECARE is well positioned to leverage learning's & relationships from TVT to drive breakthrough results.

To become the leaders in the Pelvic Floor market, speed to market and a portfolio of products are a must.

Strong synergies with existing customer base for TVT, within the segment: Urogynae, Gynae, Urologist.

Market is changing dramatically, there is rapid entry of competitors in this market (SUI market is now starting to become in some countries a commodity market) and there is a new trend of using meshes to treat vaginal prolapse.

Pelvic floor is a growing market.

2. Objectives and strategy for Pelvic Floor Repair

The overall objective is to become the leader and most innovative company in both Incontinence and Pelvic floor procedures.

This means Gynecare is to become the leading company for Pelvic Floor repair offering a broad range of products to meet the customer's needs.

Leadership is defined as:

#1 Unit Market Share
#1 $ Market Share
The best Quality of professional education, support materials and product

Gynecare is working on a multigenerational product and procedure approach to meet all the needs of the customer.

Today Gynecare provides GYNEMESH PS as a state of the art implant. This allows surgeons to tailor their own personal Graft repair with a shapable inert, soft implant with PROLENE at the core.

3. Market Overview

3.1 Market definition

Pelvic organ prolapse is thought to result from a stretching, weakening or tearing of the soft tissue structures that support the pelvic organs.
Risk factors for pelvic organ prolapse include vaginal parity, neuropathy, obesity, excessive, chronic valsalva, connective tissue disorders, prior surgery, estrogen status and advancing age[i,ii,iii,iv]. Surgical correction of these problems is a major health care issue for women.
It is estimated that as many as 50% of parous women experience some degree of pelvic organ prolapse during their lifetime. 19MM women in the US and Europe are diagnosed and 1MM (5%) women currently seek treatment.
In addition an analysis of members of a large health maintenance organization estimated the lifetime risk of 11.1% of at least one operation for pelvic organ prolapse and urinary incontinence with a reoperation rate of 29.2%.[v]

Non-surgical interventions for prolapse management include pelvic floor exercises and pessary support.
Surgical options are numerous, made more challenging as multiple weakened regions often occur in a patient and incomplete correction of any region may lead to worsening of the other regions. The surgical procedures may involve tightening and reinforcing of weakened tissue, suspension of unsupported structures or a combination of both. The tightening/reinforcing and suspension procedure may utilize several materials including:

suture alone
autologous tissue
cadaveric material
allograft material
synthetic permanent mesh.

Worldwide it is estimated over 500,000 procedures are performed for Pelvic Organ Prolapse (POP).

Traditional surgical treatments, with sutures alone are starting to be considered inadequate with published recurrence rates up to 40%. Mesh materials have been used with great success in hernia repair by General surgeons and the Gynaecologic and Urologic communities are starting to utilize them to provide additional support to the pelvic floor where autologous tissues are not adequate, but they do add the risks of erosion and rejection.[vi]. These grafts may be placed using an abdominal or vaginal approach.

Literature reviews describing the outcome and complications associated with pelvic floor repair procedures are inconclusive. In the cases where meshes were used to provide additional support, advantages have been reported. Julian studied patients with multiple recurrence of vaginal prolapse in two groups that differed by mesh use or not. In his study, all grafts were placed using a vaginal approach. He found a decrease in the expected recurrence rate with mesh, but did observe some complications associated with the use of synthetic mesh. The erosion rate was 25%. Overall, he concluded that adding synthetic mesh was effective in these cases.[vii] Visco reported an overall vaginal mesh erosion rate of 5.5% using an abdominal approach for mesh placement. This rate was considered low when compared to historical data, which shows a 9% erosion rate for abdominal mesh placement.[viii]

The abdominal approach to repair of pelvic organ prolapse uses one of two procedures, the abdominal sacral colpopexy or the abdominal sacral colpoperineopexy. These two procedures have the highest long-term success rates of any surgical procedure for pelvic organ prolapse.[ix,x,xi] Both procedures involve enveloping the vaginal vault with a graft material and then attaching the grafts to the anterior longitudinal ligament over the sacrum. These procedures attempt to restore the normal connective tissue support to the vagina by replacing the damaged connective tissue with a graft.
Problems with erosions of permanent mesh placed in the body are not unique to pelvic surgery.[xii,xiii] Several factors are thought to contribute to mesh erosions including a poor healing environment influenced by nutritional status and blood flow, infections, foreign body reactions, and mesh characteristics such as rigidity and mesh density.

Currently today these procedures are divided between Plication (tissue to tissue suturing) and reinforcement with grafts (cadaveric grafts, autologous grafts, xenografts, animal derived grafts, synthetics). From the surgical procedures standpoint, the market includes:

Cystocele:
Anterior colporrhaphy
Paravaginal repair (vaginal & lap approach)
Graft\mesh procedure
Rectocele
Posterior colporrhaphy
Graft\mesh repair
Vault Suspension
Sacrospinous ligament fixation
Uterosacral ligament fixation
Abdominal sacrocolpopexy
Graft/mesh repair
Enterocele
McCaul culdoplasty

Polypropylene mesh has been the most widely used mesh in gynecologic surgery including many types of pelvic floor repair procedures.[xiv] Polypropylene meshes include Bard MARLEX Mesh and Ethicon PROLENE Polypropylene Mesh.
To address the market trend to use meshes to repair pelvic organs prolapse, Gynecare introduced in Europe a polypropylene mesh called **GyneMesh** in 1998.

In May 2003, **GYNECARE** introduced in Europe **GyneMesh PS** a second generation of synthetic Mesh indicated for repair or reinforcement and long-term stabilization of the pelvic floor or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
GyneMesh PS was launched in the United States in March 2003 as a first generation of synthetic mesh exclusively designed for pelvic floor repair surgery.

GYNECARE **GyneMesh Prolene Soft** (Polypropylene) **Mesh** (PSM) is a modified PROLENE Mesh identified as, a reduced density construction PROLENE Polypropylene Mesh. *(need to add data from the 1 year follow up US study)*

3.2 Market size

US

Year	2003	2004	2005	2006
Applicable procedures	242,300	252,000	262.100	272.500
Number grafts sold	18.500	32.300	25.700	35.400
% Penetration	7,6%	12,8%	9,8%	12,90%

These numbers of penetration up and down 2004-2006 need fixing

EU

Year	2003	2004	2005	2006
Applicable procedures	208.000	216.300	225.000	234.000
Number grafts sold	14.600	21.600	33.300	39.800
% Penetration	7,0%	10%	14,8%	17,0%

Source: TVM financial model 010701.xls

3.3 Market dynamics

In both the EU and US, techniques for prolapse surgery using meshes have been under development for several years. Key EU countries are at different stages of development with respect to the use of mesh for prolapse repair, but techniques which gain acceptance in one country often spread rapidly to the others.
In the US, the use of synthetic materials for the treatment of prolapse has also been under development for a number of years. KOL opinion's on the use of synthetic materials for prolapse repair are a various stages of development and acceptance. However at this point in time, there are many techniques and products currently being utilized and no clear consensus has been reached on both materials choice and technique.

Current limitations today are high recurrence rates, higher than required erosion rates and non-standardisation of technique making it hard to adopt but the market unmet needs are high.

Gynecare's challenge is to enter the market with a product *and* technique that will allow gynecologists, urogynaecologists, and urologists to perform a quick, efficient, effective (long term reduced recurrence rate, consistent outcomes), safe (low erosion rate) and reproducible procedures for the treatment of these pathologies. It is felt that the GYNECARE Prolift product and technique, supported by the results of the pending clinical study, will address these market needs.

4. Product overview

4.1 TVM – Procedural Overview

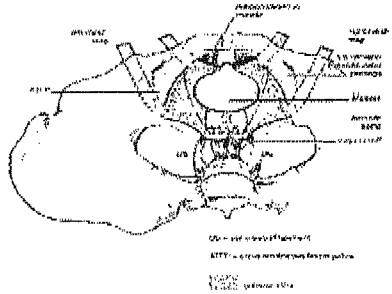
The **Trans-Vaginal Mesh** (called **TVM**) procedure is the result of the work of a group of 9 french physicians (Dr J. Berrocal, Dr H. Clavé, Dr M. Cosson, Dr P. Debodinance, Dr O.Garbin, Pr B.Jacquetin, Dr C. Rosenthal, Dr D. Salet-Lizée, Dr R. Villet) who had extensive experience in pelvic floor repair and the use of mesh through vaginal route, lead by Pr Jacquetin on the initiative of Axel Arnaud. It started in 2000 and every time they were meeting they would go to one of the group members to observe prolapse repair surgery.

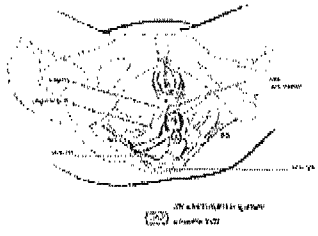
It is expected to be the next evolution in POP repair. It utilises a GYNEMESH PS implant that has been developed over 2 years and will adress anterior, vault, posterior and total repairs.

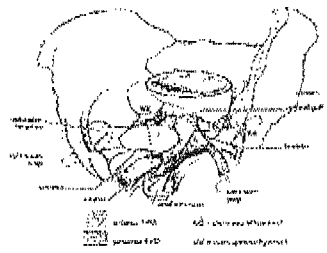
The aim of the procedure is to provide a standardized implant for Grade III and IV POP with a low tissue reaction and soft synthetic implant .
The procedure has been created to be simpler to teach and reproducible in a wide variety of patients while ensuring them consistent outcomes.

It is performed through vaginal route and mesh is held in place by a series of straps to sustain pelvic defects.
Initial incisions are performed through the anterior and/or posterior walls of the vagina (depending on anterior repair only, posterior repair only or total repair). The tissues planes are dissected and organ prolapses reduced. The correct implant is selected and then placed.
Anterior only, posterior only and total repair techniques are described on the below drawings:

Anterior repair: single anterior mesh, two bilateral arms through the obturator space in the arcus tendineus	**Posterior repair:** single posterior mesh, one bilateral arm through the sacrospinous ligament	**Total repair:** posterior and anterior mesh in place







4.2 Gynecare Prolift ™ Instruments and Implant Overview

The following components will be part of the kits:

GYNECARE GYNEMESH* PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Total Mesh Implant

The Total mesh implant is GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant through the obturator foramen and two for securing the posterior portion of the implant to the sacrospinus ligament via a trans-gluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and the implant can be secured via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends. See *Figure 1*.

Anterior Mesh Implant

The Anterior mesh implant is GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a trans-obturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively. See *Figure 1*.

Posterior Mesh Implant

The Posterior mesh implant is GYNECARE GYNEMESH PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured to the sacrospinus ligament via a trans-gluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and the implant can be secured to the sacrospinus ligament via a vaginal approach. The posterior straps have rounded ends. See *Figure 1*.

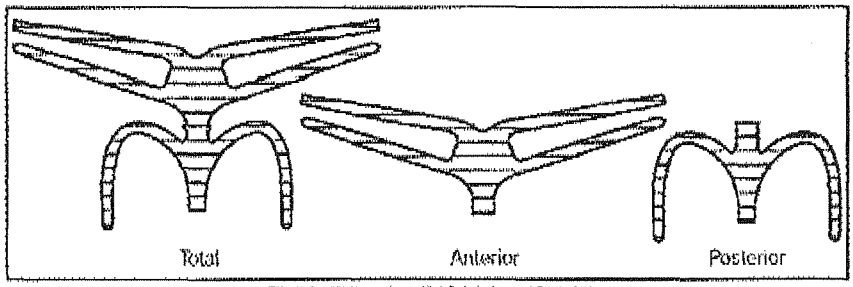


Figure 1 – Mesh Implants (Total, Anterior and Posterior)

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

GYNECARE PROLIFT Guide

The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create a path to allow placement of the Total, Anterior and Posterior mesh implants and to facilitate the placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to allow for the proper placement path for the mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient. See *Figure 2.*

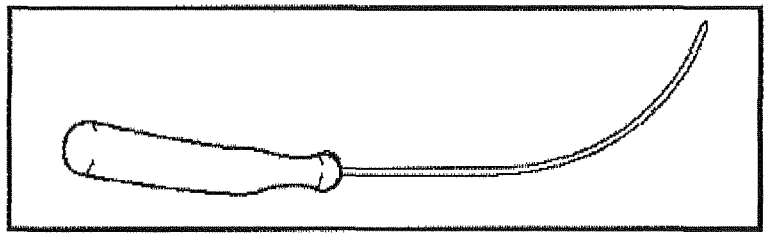


Figure 2 – GYNECARE PROLIFT Guide

GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn. See *Figure 3.*

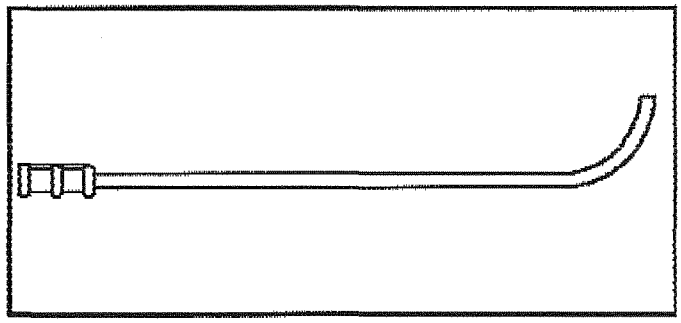


Figure 3 – GYNECARE PROLIFT Cannula

GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula. See *Figure 4.*

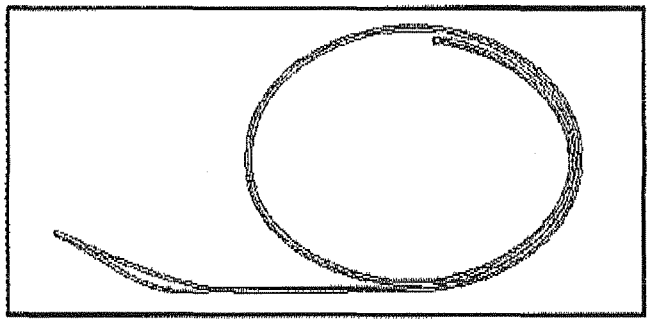


Figure 4 – GYNECARE PROLIFT Retrieval Device

There will be three different kits available for performing TVM

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT Repair System Components

4.3 Key product features and benefits

Key Feature	Key Benefits
GYNECARE GyneMesh PS Implant	Proven safe material Allows rapid fibrinous fixation and excellent tissue ingrowth AMID type 1 mononfilament mesh which is the preferred implant for pelvic floor surgery (NICE)
Standardized procedures	Proven effectiveness (less incidence of recurrence) Easy to perform More anatomically correct repair which should lead to better function Standardized procedure to achieve outcome Lower recurrence rates Shorter OR time compared to complex repairs Practice expansion due to growing patient population
Anterior transobturator approach, Posterior approach, total repair approach	Provide the greatest possible flexibility to users Adresses all types of repairs: prophylactic or not
Pre formed mesh implant	Optimal repair Reduce time for preparation Ease of placement, use
One Guide for all passages	Anatomically designed Facilitate accurate introduction and smooth, continuous passage of the mesh Thin diameter needle to allow atraumatic passage in tissue
Retrieval lines	Use in pulling the Mesh Implant fixation straps through the Cannulas Facilitate passage of the straps in the cannulas Easier to grasp than suture
Plastic cannulas	Facilitate proper, atraumatic placement of the Mesh Implant fixation straps Reduce tissue tearing

5. Product Positioning

GYNECARE *Prolift* kits will be positioned as an innovative, efficient, safe, standardized apical, anterior, and posterior vaginal defect repair procedures for physicians who are looking for an effective, clinically proven standardized prolapse repair procedure with consistent outcomes. It will complement the GyneMesh PS product and as such will contribute to create a Gynecare full range of products for prolapse repair addressing each segment of the market (anterior, vault/apical and posterior repairs).

Most importantly, it will be positioned as fulfilling all the critical success factors needed for a procedure to become a gold standard: (Our strongest position is: The only clinically supported Prolapse repair utilizing a synthetic mesh with 1 year evidence of safety)
-ease of use
-greater efficacy than current procedures performed (presumed not proven – cannot claim)
-short term and long term efficiency (do mean efficacy? Not proven yet. Cannot claim)
-safe and reproducible procedure
-meeting an unmet need (yes. A procedure that supports the critical principles of a good repair: a) good coverage of the defect, b) apical support, c) "tension free" repair with natural attachment that allows restoration to the "normal anatomical position"
-high patient satisfaction (not proven yet, cannot claim)

In addition the following will be our positioning statements:

GyneMesh-PS

Proven Implant because
- Prolene – tried and tested (inert, US GyneMesh study 1 year results)
- Soft – Less erosions (reduced erosions compared to other materials)
- Optimised (Specifically designed) for pelvic floor

TVM (Trans-Vaginal Mesh) procedure

Best Procedure because
- Standardized for reproducible outcomes that have been clinically evaluated
- Anatomically correct
- Flexible (comprehensive offering of solutions – Ant / Post / Total, and flat mesh)
- Tried and tested (clinical data) – safe (& effective – cannot claim yet)
- KOL endorsed

Gynecare Prolift Kit

Best delivery devices because
- Atraumatic delivery system – Sheathed needles
- Unique needles – anatomically designed and tested
- Simplified mesh placement – (no sheaths on mesh to remove – careful with this as a sheath for TVT is good. Let's claim – Simplified & smooth mesh placement – cannula & retrieval system)
- Unique fastener technology – multiple approaches offer physicians flexibility & choice

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Best Education

Best training because
- World class Preceptor network – Live trainings
- State of the art training materials
- Advanced training courses – combined procedures with TVT
- Evidence-based medicine to support our innovation & training

GyneMesh PS will continue to be marketed as the "state of the art" implant for the physicians who prefers to perform their "own" technique.

6. Targeting

The targeting and follow-up of the physicians Gynecare want to engage early on as well as the physicians who will be trained once the product is launched will be key critical success factors for future spreading of the technique.
As this procedure is new, Gynecare must make sure to establish the foundations of KOL engagement and advocacy to have the Trans-Vaginal Mesh technique become a gold standard.

Main reasons for physicians to switch to Gynecare Prolift range of product are:
- Efficient restoration of anatomy
- Reproducible procedure: speed and ease of use backed by clinical evidence & experience
- Low complications rates (short term & long term): low erosion rate
- Low long term recurrence rate (cannot claim this)

Anterior repair:

Phase	Target selection criteria
Phase 1: Pre launch Preceptors KOL High volume GyneMesh PS customers	-Gynecare friendly -50% of practice is pelvic floor -has experience in teaching pelvic floor surgery (preceptors) -currently using GyneMesh PS -doing transobturator SUI surgery or knowledge of the anatomical transobturator space
Phase 2: Launch	-50% of practice is pelvic floor -currently using grafts (not only mesh) (first target mesh users, secondary target using biologics) -doing transobturator SUI surgery or knowledge of the anatomical transobturator space

Posterior repair:

Phase	Target selection criteria
Phase 1: Pre-launch	-Gynecare friendly

Preceptors KOL High volume GyneMesh PS users	-50% of practice is pelvic floor -has experience in teaching pelvic floor surgery (preceptors) -currently using GyneMesh PS -doing sacrospinofixation (sacrospinous fixation) (Richter) -doing or has done IVS posterior
Phase 2: Launch	-50% of practice is pelvic floor -currently using mesh (first target, secondary target using biologics) -doing sacrospinofixation (Richter) -doing or has done IVS posterior

Total repair :

Phase	Target selection criteria
Phase 1: Pre-launch Preceptors KOL High volume GyneMesh PS users	-Gynecare friendly -50% of practice is pelvic floor -has experience in teaching pelvic floor surgery (preceptors) -currently using GyneMesh PS (and comfortable using large graft materials for repair) -doing transobturator SUI surgery or knowledge of the anatomical transobturator space -doing sacrospinofixation (Richter) -doing or has done IVS posterior
Phase 2: Launch	-50% of practice is pelvic floor -currently using mesh for anterior and posterior repair (first target, secondary target using biologics) -doing transobturator SUI surgery or knowledge of the anatomical transobturator space -doing sacrospinofixation (Richter) -doing or has done IVS posterior

7. Pricing

Worldwide pricing of GYNECARE *Prolift* anterior, posterior, total kits has yet to be finalized according to the global pricing process in place.

The pricing of the PROLIFT procedure kits will be based upon the extreme value that this new procedure delivers to the end user as well as what the end user perceived value is. It will also have to take into account the health economic environment of each countries.

A pricing research study done by an external company has been ordered which includes VOC and healthcare environment price constraints. In parallel, the Gynecare Health Economics & Reimbursement department will give its recommendations for US & EU countries.

Based on thoses findings, the launch team will submit its recommendation to the Global Pricing Committee who will decide on the final products price.

In the financial model, the rational used for the pricing was based on current competitive devices already in the market:

US:
-for the anterior or posterior stand alone repair kits, the reference average selling price was 500$ (SUI devices average selling price is 600$)
-for the total repair kits, the reference average selling price was 750$ (1,5 times the stand alone kits)

EU:
-for the anterior or posterior stand alone repair kits, the reference average selling price was 400$ (SUI devices average selling price is 400$)
-for the total repair kits, the reference average selling price was 600$ (1,5 times the stand alone kits)

Due to health economics reimbursement issues, it is anticipated there will be room for increasing the price in EU which will be most probably unequal among countries and limited while in the US it should be much greater.

8. Competition Overview

Currently the grafts are split between non-synthetic (biologics), hybrid (synthetic coated with collagen) and synthetics material.

Main reasons for using a non synthetic or hybrid material are the presumed benefits of:
-reduce tissue reaction
-tissue rejection
-reduce adhesions

Main reasons for using a synthetic mesh are:
-long term implant
-high tensile strength
-no risk of prion contamination
-consistent, predictable performance of material
-lower cost

8.1 Competitive landscape:

Biologics	Hybrids	Synthetics
Bard	Bard/Sofradim	EPD
AMS		Gynecare
Mentor		Tyco
Boston Sc		AMS
Cook		Sofradim

US: competitive landscape

Company	Products Offering	Price	Share	Units	Dollars $MM	Anticipated Initiatives
BARD	Pelvisol	$800-$950	30%	5547	34.4	Clinical data, Expand Prof Ed & launch Pelvisoft + synthetic
J&J	Reptiform	$950	18%	3328	$3.3	Expand sales force + contracts
TYCO	IVS Posterior	$600	16%	3325	$2	Expand Prof Ed, launch total PFR, sell 2 for 1 with GUI
Mentor	Tutoplast	$1900	6%	1108	$2	Co-sell w/Obtape
AMS	Straightline InteMesh InfoXen InteDerm	$895 $600 $900	5%	924	$0.92	Co-sell with Monarc, Expand offerings
COOK	Surgisis	$250-500	5%	1108	$0.39	Co-sell w/Stratasis TF

EU: competitive landscape

Company	Products Offering	Price	Countries	Est'd Mkt share (value)	Anticipated Initiatives
BARD	Pelvicol	€500-€230	EU	25%	Clinical data; launch of a pelvicol SUI device end of 2003
TYCO	IVS Posterior Surgipro	€650-€320 €50-€80	EU	15%	Prof Ed; Launch of a new prolapse repair procedure 2004-2005
ETHICON	Gynlex Parietex	€400-€250 €300-€200	France Germany	5%	Leverage with Ureterx; clinical data; Launch of a total repair procedure in 2005
Local competitors: COUSIN, Swiss, Angiologics,...	Intramesh Cystosewing... Angiologics mesh	€160-€350 €350 €200	France Italy	5%	Agressive attacks: price discounts; surgeons' incentive Tailored meshes
ETHICON	Prolene Marcilene Vypro	€60-€80 €70-€80 €70-€80	EU	15%	No focus in gynae
AMS	InfoXen	€400-€260	EU	Not significant	Launched in February 2004; leverage with Monarc
COOK	Surgisis	€500-€250	EU	Not significant	Leverage with Stratasis

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8.2 New comers in 2004-2005

Other competitors companies have recognized the large potential and market need for a standardized prolapse repair procedure product and search for the 'ideal implant'.

Q1-Q2/2004

SOFRADIM/BARD launched the first hybrid implant (synthetic implant coated with collagen) UGYTEX/PELVITEX in Europe and the US. As the graft market is divided into biologic implant users and synthetic implant users, this product was addressing both segments at one time. However, there is at the moment no clinical data published on the use of this prosthesis for prolapse repair.

Main features and benefits claimed by the company's product are:
-reduce erosion rate
-reduce adhesions
-durable implant

Q3-Q4/2004:

AMS recently launched two prolapse repair procedure kits (one for anterior and one for vault repair) available with two different implants materials. They are not only targeting synthetic mesh users but also biologics mesh users bringing more potential customers to their business. However, the long term benefits of biologics are unknown therefore long term efficacy is uncertained.

AMS Perigee Transobturator Anterior Prolapse Repair System

IntePro, inteXen meshes

AMS Apogee

Vault Suspension System – Synthetic Mesh

Perigee IFU.PDF Apogee IFU.PDF perigee.pdf apogee.pdf

2005:

SOFRADIM (distributed by BARD in many countries including the US) is currently working on a total repair procedural kit with Dr Delorme (T.O.T. inventor) and Dr Eyglin. They are expected to be launching a new product Q3 2005

TYCO is also expected to launch new mesh materials in 2005 and is working on a total repair procedure called T.O.P.P. with Dr Von Theobald (IVS preceptor for EU).

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In the long future, it is foreseen the quality and outcomes of the implant will become a primary criteria of choice for physicians and make the difference.

8.3 AMS Rebuttal Strategy

They key attack strategy against AMS will be the TVM (Trans Vaginal Mesh) group credibility, robust procedure development and work accomplished since 2000, the differentiation of the technique (transobturator passage of the helical needle of the AMS product), added value of the different Prolift instruments (based on cadaver labs feedbacks) and lack of clinical experience (300 cases, 1 year data versus no data for AMS).
This will be coupled with the further reinforcement of the GyneMesh PS implant, through published clinical evidence (AUGS abstract, publication in scientific magazine on 1 year follow up) and all the additional added value benefits offered by a J&J company.
An aggressive pre-launch activities plan to engage early on key opinion leaders, high volume Gynemesh PS customers and create awareness will complement it .

9. Pre-launch strategy

9.1 Customer Communication
In an effort to accelerate adoption and create a faster brand awareness and counteract competition new product launches, Gynecare has decided to start a series of pre launch events communicating on the work done with this group of 9 physicians to develop a Trans-Vaginal Mesh technique with GyneMesh PS implant:

Date	Events	Attendees
July 30th 04	AUGS- San Diego Gynecare Symposium Speakers: Dr Miller (US investigator), Dr Cosson(FR investigator) SymposiumProgramDescription.doc	80 gync, urogynac surgeons attended
Aug 23rd 04	ICS/IUGA GynecareTVM breakfast Speakers: Pr Jacquetin, Dr Cosson (FR investigators) TVMinvitationletter.doc Feedback form ICS PELVIC FLOOR MEETING.doc	45 european KOLs Participants.xls

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	Live surgery during ICS/IUGA: Pr Pigné's procedure with GyneMesh PS Dr Cosson to perform live a case with TVM procedure Workshop13 ICS04.doc	200 attendees 350 attendees
Sept 22nd 04	Cercle Récamier-Lyon Live surgery with Dr Cosson ProgrammeRécamier pdf	150 attendees
Oct 20th 04	Gynecare UK Study day Pr Jacquetin to present TVM technique and results	100 UK physicians
Nov 12th 04	One day internal training for D4, umbrellas	MM, CM
Nov 13th 04	AAGL symposium Live surgery case performed by Dr Lucente commented/moderated by Dr Miller (US investigators)	80 physicians expected

Due to the increase in competitor activity from AMS especially it is critical to have a consistent rebuttal strategy against Perigee and Apogee's products:

Key Questions for surgeons interested in AMS

- What evidence is there on the implant you are leaving in the patient?
- What clinical evidence is there on the procedure proposed? What is the long term follow-up? How many cases have been performed with those procedures?
- Are the devices proposed adapted to the procedure?
- How do they address the posterior repair? Total repair?

GYNECARE's response to Perigee/Apogee

- Acknowledge there is an unmet need for a standardized procedure for anterior, posterior, total repairs
- A current development address's this concern
- A group of nine French physicians who had extensive experience in prolapse repair and use of mesh has been working with Gynecare since 2000 to develop such a procedure
- A multicenter clinical trial is undergoing/underway to prove consistent outcomes (Independent of the physicians-own experience, a prospective trial involving 180 patients is near completion and forms the basis for the launch of the GYNECARE Prolift system
- It will be introduced with the added reassurance of the only 'tried and tested mesh implant and procedure'

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9.2 Pre-launch countries involvement and key activities:

Involving countries prior to launch of the Gynecare Prolift product range will be critical to ensure a successful launch. (Explain upfront that you are recommending a 3-Phase Launch to ensure that the GYNECARE ProLift System is introduced sequentially in countries that have an established mesh market. This will enable 2nd and 3rd Phase markets to strengthen their mesh advocates before launching ProLift)

(Countries were informed of the intended launch via the Global Marketing Council held in Paris on August 22nd, 2004). All countries will be informed on the pre-launch activities that will take place and will have the opportunity to involve surgeons early on.
However, key activities will be available for countries where the Gynecare Prolift range of products will be launched during Phase 1 (Soft launch: February and Full launch: April 05).

The Gynecare Prolift product range will be launched in Phase 1 in the US, EU D4 countries, Australia and three umbrellas (Spain, Benelux, Switzerland). As level of mesh penetration is unequal among countries (umbrellas, Asia), the countries with the highest mesh penetration rate will launch in Phase 1 while the other will launch once they have developed the use of GyneMesh PS.
Phase 2 will start in late September and will include: Portugal, South Africa, Scandinavia, Austria, some Asian countries and Canada.(waiting this long for Canada may be an issue)
Phase 3 will start in 2006 and will include: ROW, Eastern countries, Latin America...

Pre-launch and soft launch countries activities includes:

Monthly e-newsletter distribution
Symposium (TVM breakfast at ICS/IUGA, Live surgery)
Observe surgery in Lille or Clermont Ferrand
Internal training for MM or CM

9.3 Pre Launch Preceptor Programme (US, D4, Umbrellas phase 1)

Activities	Date
Preceptor Selection	17/09/2004
Preceptor Engagement	9/17/2004 - 10/15/2004
Cadaver Labs US	10/15/2004 - 12/15/2004
OR Training EU	9/27/2004 - 12/7/2004

Objective
FDA/CE marked Prolift product for human clinical use will not be available until end January 2004/**2005**, in order to defend any further existing business from either posterior IVS, Perigee, Apogee or any other implants procedures, there will be a Prolift Pre Launch Training Programme to start enrolling future preceptors, KOL, high volume GyneMesh PS customers.

Programme

- Capacity to take a further 40 surgeons to Lille (mostly) or Clermont Ferrand between Oct-Dece 04
- Average 3-4 surgeons per visit
- Global Launch Leader and local CD/MM to attend sole country visits
- Evening arrival, following day observe and participate to surgery 2/4 procedures in the OR with a presentation of the physicians results
- The aim of the mixed country visit is to give 'extra importance' to the customer exposing them to a European group and to also diffuse the positive experiences
- Countries will still be given the opportunity to reserve one session for their customers only
- The EU training will focus on OR observation (11 sessions) with inventors in France while US training will focus on cadaver lab (1 lab) and few surgery observations (1 session) in EU for 'VIP' only (what about using the US investigators by December for a live surgery program?)

Proposed dates in Lille with Dr Cosson

27/28th September	Mixed European Visit
5th October	Umbrella Visit
19th October	Mixed European Visit
2/3th November	Mixed European Visit/US
16th November	Mixed European Visit
23/24th November	Mixed European Visit
30th November	Mixed European Visit
7th December	Mixed European Visit
11th December procedure training	Mini summit cadaver lab in Las Vegas/US and

10. Launch strategy milestones

10.1 Product availibility

Release of Reusable Guides For First Human Use (Pr Jacquetin, Dr Cosson, Dr Debodinance)	Mid Oct
Design Verification	
Packaging complete	Sept 04
IFU complete	Sept 04
Demo product availability	Mid Nov 04
Limited Quantity Release Of Pilot Devices For First Human Use (30 kits)	Mid Dec
Design Validation	Dec 04/Jan 05
510k submission	Mid Nov
-Approval (11/1 or 1/1)	
IQ/OQ/PQ	Aug 04 – Dec 04
-(Sterilization and all other processes at Mediline, JEB, & Neuchatel)	
CE mark	Jan 29th 05
PRA Approval For US and EU(Beta Launch)	Jan 29th 05

10.2 Pre-launch/Launch activities

AUGS symposium	Jul 04
ICS/IUGA breakfast	Aug 04
Cercle Récamier	Sept 04
Train future preceptors	Oct-Dec 04
Gynecare UK study day	Oct 04

AAGL symposium		Nov 04
Pre-training of EU/Umbrella		Nov 12th
Cadaver labs/Mini Summit		Dec 04
Soft Launch		Jan 29th
Full product available/Release to preceptors		Jan 29th
EU Live surgery with preceptors/Train the trainers programme		Feb 05
Soft launch Training US team		NTM
Soft launch training EU team	Feb 05	
TVT Preceptor Summit	Feb 05	
Clinical data availability	March 05	
Tools available	March 05	
Start Training sessions	March 05	
Full launch	Apr 05	

(There must be a plan to have a webcast/training for the US sales force in Q4 2004 to share our plans for D'Art, help the DM's/reps to understand the advantage and positioning of our product, begin looking for the right target doctors and also "rebut" the competitor's products…)
See attached Gantt charts (Appendix 2)

11. Professional Education

11.1 Internal Training

As prolapse repair is very complex, it is expected learning the TVM procedure will take more time than for SUI procedures to learn. Therefore, the training will occur in different phases:

EU:
1) Exposure to the pelvic floor platform opportunities and future product launches last May 2004 during the umbrella meeting
2) Involvement of local management (Marketing Managers and Sales Managers) and training on prolapse repair through a one day pre-training course in November 12th

This will assist the sales team to clearly understand and learn the anatomy, the reason for the use of meshes, the different techniques in prolapse repair and competitors product prior to launch meeting. The content will detail:

- Anatomy
- What is a prolapse?
- Surgical treatments including techniques using grafts or not grafts
- Reasons for the use of meshes, criteria of choice for the implant (Gynemesh PS differentiation)
- Techniques using meshes and competitive products
- Gynecare Prolift procedures
- Pre-launch /launch strategy

3) Soft launch for sales force and training on prolapse repair through a 12 hours training during the next European meeting in February. The course will use the content taught in November adapted by local marketers.
4) Full launch during local sales meeting in April

US:
1) Involvement of sales and marketing management on prolapse and pelvic floor strategy
2) one to two hours training course on anatmy and prolapse repair techniques during US regional meetings in July 04
3) Soft launch and training course on prolapse repair and TVM procedure the next NTM in late January
4) Full launch during local sales meeting
(There must be a plan to have a webcast/training for the US sales force in Q4 2004 to share our plans for D'Art, help the DM's/reps to understand the advantage and positioning of our product, begin looking for the right target doctors and also "rebut" the competitor's products. Waiting until January will be too late – this will help to capitalize on the AUGS workshop as we should be following up to get feedback.)

Launch material will be prepared which will cover the following areas. (let's make sure we are not leaving too much for the "local" team to develop – our US resources on the Global project are also the local resources, and Joe will have to support many umbrellas…)

- Background to local market (Local MM to prepare)
- Review of anatomy (Local MM to adapt content given)
- Review of prolapse repair most used techniques locally (Local MM to adapt content given)
- Background to launch of GYNECARE Prolift (Local MM to adapt content given)
- Detailed description of procedure (Local MM to adapt content given)
- Key features and benefits (Local MM to adapt content given)
- Clinical Evidence (Local MM to adapt content given)
- Competition Rebuttals (Local MM to adapt content given)
- Review of literature: on meshes, techniques, competition (Local MM to adapt content given)
- GYNECARE Prolift Positioning & Price (Local MM to adapt content given)
- Promotional Material (Local MM to adapt content given)
- Q&A (Local MM to adapt content given)
- Next steps – Targeting & surgeon Prof Ed & Follow up (Local MM to prepare)

11.2 Surgeon Training

In January 05 when GYNECARE Prolift product range will be available there will have been over 40 surgeons across Europe who will have attended the Pre Launch Preceptor Training in Lille or Clermont Ferrand as well as well as 30 surgeons who will have attended a cadaver lab in Las Vegas and/or gone to Lille for training.

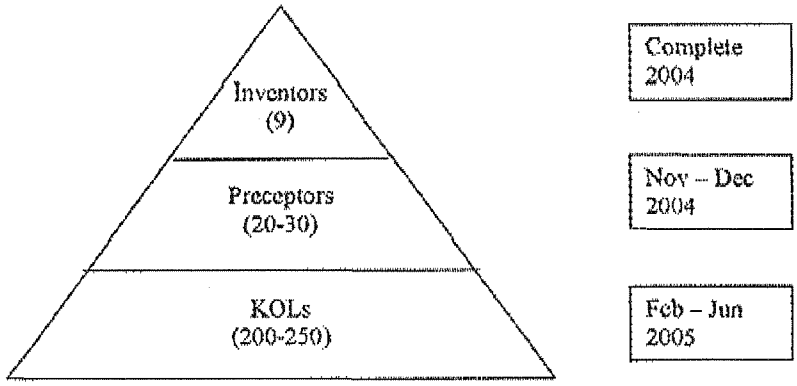
EU:

Activities	Date
Preceptor Selection	17/09/2004
Preceptor Engagement	9/17/2004 - 10/15/2004
OR Training EU Pre Launc	9/27/2004 - 12/7/2004
Preceptor Live surgery	1/29/05-2/13/05
OR Training EU	9/27/2004 - 12/7/2004

During Soft Launch in February, Gynecare will organize a live surgery event as well as a teaching session on content that will be given to preceptors. This will give the opportunity to bring together the surgeons who have agreed to become Preceptors in order for them to clearly understand the 'cook book' technique in order to then continue to teach the correct procedural steps, which will then create the pyramid of training. They are expected to perform 5-8 procedures in February-early March before they start training in March-April. (To make this a little more exciting, it might be nice to ask the US investigators what they think about starting with M. Cosson operating on a Live Telecast from France and having the US investigators be the local moderator – we can use Dave Robinson for West Coast, Dennis Miller for Mid-west and Central Region, and Vince Lucente for East Coast)

In addition each country will be able to arrange local launch/webcast/symposium and given the opportunity to invite Pr Jacquetin or Dr Cosson (an at least two month notice will be required to ensure inventors availability).
Each market will then be required to execute their own Professional Education with local preceptors (2-3 centers) who had been enrolled on earlier activities (OR observation, live surgery).
Training with 'key' or 'VIP' surgeons being invited to Lille or Clermont Ferrand will still be an option but will be limited due to capacity issues.
A flying program will also be set up to give more flexibility to countries, Dr Debodinance will do most of it (an at least two month notice will be required to ensure inventors availability).

Our aim is to create a preceptor pyramid-training program:



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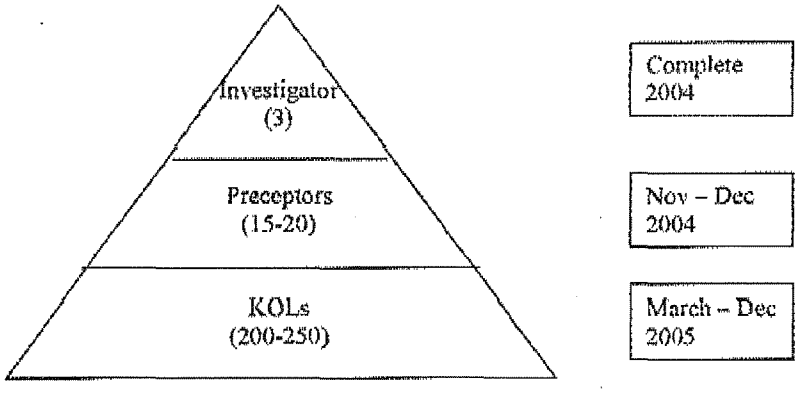
US:

Activities	Date
Preceptor Selection	17/09/2004
Preceptor Engagement	9/17/2004 - 10/15/2004
Cadaver Labs US	10/15/2004 - 12/15/2004
OR Training EU	9/27/2004 - 12/7/2004
OR Training US	3/3/2005 - 15/12/2005

From mid January to February, Gynecare will organize for the physicians who attended the cadaver lab (25) in Las Vegas to go observe surgery in one of the 3 US investigators sites. It is expected each physicians will use the product 5-8 times before they feel confident with the technique during February-early March. In addition, a webcast to train future preceptors (10-15) on training content will be set up once tools will be available.
Each preceptor is expected to train 3-4 physicians a month. Complementing OR surgery observation with cadaver lab will be pursued if feedback from surgeons who attended the one organized in Las Vegas shows it brings value to the training.

Our aim is to create a preceptor pyramid-training program:



This will allow us a controlled roll of this complex procedure but create enough users to achieve our first year sales target.

(NB. All users of TVM MUST go through our preceptorship programme in the US and ARE RECOMMANDED to go through our preceptorship programme in EU)

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12. Clinical Strategy

To date there is now 1 abstract on TVM technique at IUGA/ICS . Dr Debodinance is submitting one article on technique in a French scientific magazine.

Regarding GyneMesh PS publications, many abstracts can be found (AUGS, ICS/IUGA) and one/two scientific papers (one abdominal, one vaginal paper) is under writing for a potential submission in an American scientific magazine in late November.

A prospective multicenter clinical study is undergoing with 3 US investigators (Dr Miller, Dr Lucente, Dr Robinson) and 9 French physicians (Pr Jacquetin, Dr Cosson, Dr Debodinance, Dr Berrocal, Dr Garbin, Dr Clavé, Dr Rosenthal, Dr Villet, Dr Salet-Lizée) on 180 patients with 6 month, 1 year, 3 year and 5 years follow up.

Gynecare aims to launch the TVM procedure with a set of clinical data therefore for the launch of GYNECARE Prolift, the 6 month clinical data will be available as well as a monograph of the technique. Both the above evidence and the monograph by Pr Jacquetin and the TVM group will adequately support safety and efficacy of the procedure. However, further published results will be necessary to support clinical evidence. Dr. Joel Lippman has agreed to meet with the clinical and marketing team in Q4 to flush-out the publication strategy as well as discuss what data can be made used for launch.

As of today, more than 300 cases have been performed by the group of 9 physicians. The group has collated its data and is anticipated to submit it for publication towards end 04.

Post launch customer initiated research studies have yet to be determined. A need for further clinical study to be undertaken has already been identified and will need to be budgeted for 2005.

13. Launch Materials

The below items are currently in development and are planned to be available for the launch of GYNECARE Prolift:

Support material	Description	Availability
4 pages detail aid	Description of tools, presentation of features and benefits of the technique, Gynemesh PS implant characteristics, clinical results and characteristics	Dec 04
High res photo images/Photo library	To be used in brochures, presentation	Dec 04
Key procedure steps	Describe technique and key steps	Dec 04
OR staff sales aid	Describes patient preparation, instruments needed to perform procedure, anesthesia protocole, etc	Feb 05
Development of print adverts	Coming soon teaser and launch advertising campaign	March 05
Interactive CD Rom	Case study style format with videos of procedure, cadaver dissections, 3D anatomy and MRI	March 05

TVM technique Monograph	Authored by Pr Jacquetin and the group of 9 phycisians To support clinical evidence on the procedure: describes evolution, instruments, procedure, anatomy, clinical data	Feb 04
Preceptors PWP presentation	Presentation to support preceptor training on the technique	Feb 05
Preceptee binders	To be handed out after preceptorships, includes CD, product information, clinicals, monograph	March 05
Competitive matrix for salesforce	One page with all competitors tools and mesh characterization	Dec 04
Prolapse repair training CD rom	3D CD rom to train on prolapse repair	Dec 04
Launch binder		
Mesh bibliography	Bibliography classified according to competition, complications/themes, date of publication with summary to strengthens argumentation	Dec 04
FAQ for salesforce	Adresses how to handle intraoperative or postoperative complications, patient selection, clinical data	Feb 04
Convention marketing salesaids	Prospecting cards, booth posters, promotional giveaways	March 05
Pelvic models	Models used for enhanced training experience. Not custom made.	Oct 04
Patient leaflets	Build awareness of prolapse, failure rates, mesh benefits, patient options, call to action	March 05

14. Exhibition Strategy (from now on)

Where	When	Presenter	Details
Cercle Récamier/Lyon-France	Sept 04	Dr Cosson	Live surgery ProgrammeRécamier pdf
Gynecare UK study day/York	Nov 04	Pr Jacquetin	Presentation
AAGL/San Francisco-US	Nov 13th	Dr Lucente/ Dr Miller	Live surgery
JPEG/ Paris	Feb 04	Pr Jacquetin	GYNECARE Symposium organized on prolapse techniques
/Dunkerque-France	27-28 th Feb 04	Dr Debodinance/Dr Cosson	Live surgery and round table
EAU	March 05	Dr X	L
Austria	March 05	Dr X	Live transmission
ICS 2005	Date (Canada)	Prof X	What we will present etc

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IUGA 2005			
AUGS 2005			
etc			

15. Product logistics

15.1 Inventory

GYNECARE Prolift will be supplied from Neuchâtel, Switzerland. The team in Gargrave, UK, which is led by Richard Noble, is currently managing the demand planning .
Rachel Geiser will continue to be the contact for the purchasing department

Product Code	Description	Case Contents
PFRA01	*GYNECARE Prolift Anterior Pelvic Floor Repair system*	1
PFRP01	*GYNECARE Prolift Posterior Pelvic Floor Repair system*	1
PFRT01	*GYNECARE Prolift Total Pelvic Floor Repair system*	1
PFRF01	*GYNECARE Profix Fastener system*	1

All components will be provided sterile and single use.

15. 2 Forecasts

The latest forecasts for GYNECARE Prolift are attached. This includes local markets safety stock, sterile and non sterile samples. The rate of cannibalization of the existing GyneMesh PS needs to be addressed in each of the local markets forecasts.
(It is quite useful to include an assumptions section as it relates to the forecast : example, timing of product availability, advocacy of large pieces of mesh, etc... This is so that if a critical assumption changes, then it will affect the forecast, and people understand that better)
See appendix 3

15.3 Samples

First build reusable guide prototypes anticipated Mid October 04 (3 samples: 1 for Pr Jacquetin, Dr Cosson, Dr Debodinance)
Final product – Non sterile samples for demos or product shooting anticipated Mid November 04
Final product – sterile anticipated mid December 04 (30 kits for US investigators and 9 FR investigators)
Final product – sterile release for sales anticipated January 29th, 2005

15.4 Pelvic Floor Sales Projections (WW)

	2004	2006	2008	2007	2008	2009	2010
WW Direct Sales							
Cystocele Net Sales ($000s)	$ 3,050	$ 3,403	$ 3,415	$ 3,037	$ 3,912	$ 4,190	$ 4,448
Anterior PFR Net Sales ($000s)	$ -	$ 1,230	$ 3,050	$ 4,844	$ 5,206	$ 6,308	$ 6,026
Posterior PFR Net Sales ($000s)	$ -	$ 1,474	$ 4,827	$ 9,000	$ 11,189	$ 12,283	$ 13,988
Total Repair Net Sales ($000s)	$ -	$ 1,811	$ 4,940	$ 9,872	$ 17,007	$ 23,181	$ 30,900
Total DFAI Net Sales	$ -	$ 4,285	$ 12,837	$ 23,755	$ 34,948	$ 42,702	$ 50,914
Total PFR Net Sales	$ 3,050	$ 7,998	$ 16,252	$ 26,392	$ 39,870	$ 46,698	$ 55,362

Source: TVM financial model 061404. Based on prices of the model, do not have sure revenues.

See appendix 1

16. Budget summary / Resources

16.1 Global Launch team budget:
All materials listed in the promotional items with be funded from the 2004 Pre Launch budget of the Global Launch Team budget and the 2005 Launch budget of the Global Launch team :

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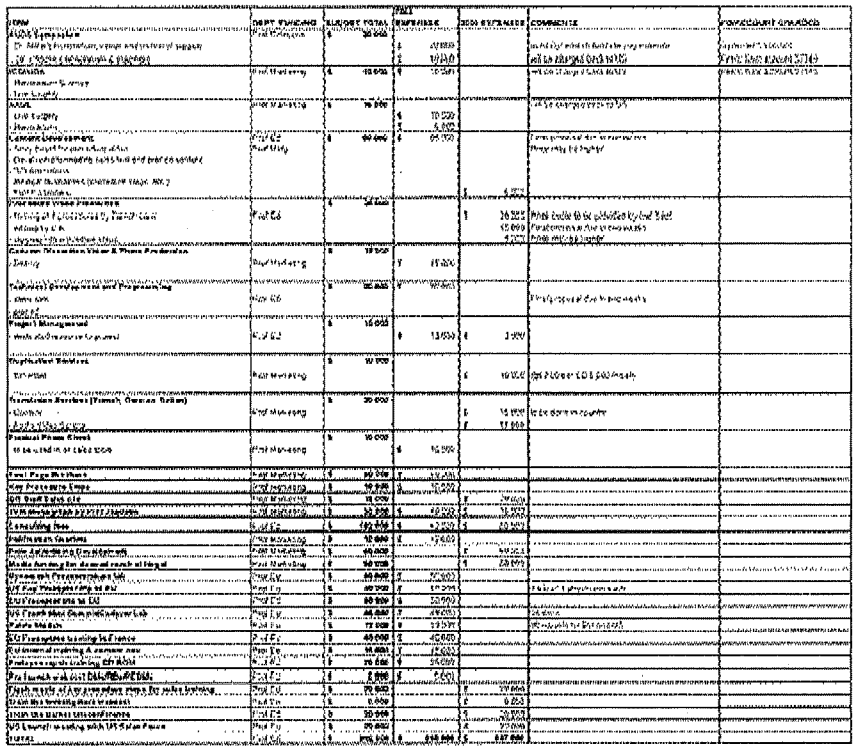
GYNECARE PROLIFT PROFESSIONAL MARKETING AND PROFESSIONAL EDUCATION BUDGET



See Appendix 4

16.1 2005 Local launch team budget:

Local launch budget should include budget for:

Phase 1 and 2 countries: Accelerating Gynecare Prolift adoption

Duplication of Gynecare Prolift tools (CD, brochures, etc)
Publication reprints (Monograph, GyneMesh PS publications, Bibliography articles)
Samples for customers or salesreps
Local launch events (Roadshows, Live surgeries, etc), workshops and exhibition
Preceptorship for GyneMesh PS and Prolift
Any other promotional items
Local consulting fees for advisory board (KOLs sponsorship)
Salesforce meeting and training tools
Salesforce incentives
Local post marketing trial

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Phase 3 countries: Develop use of GyneMesh PS

Preceptorship for developing use of GyneMesh PS
Duplication of tools for GyneMesh PS (CD, brochures, etc)
Publication reprints (Monograph, GyneMesh PS publications, Bibliography articles)
GyneMesh PS samples for customers or salesreps if needed
Local launch events (Roadshows, Live surgeries, etc), workshops and exhibition to establish GyneMesh PS brand and create awareness on Gynecare Prolift product
Any other promotional items
Local consulting fees for advisory board (KOLs sponsorship)
Salesforce meeting and training tools on prolapse repair
Salesforce incentives to drive GyneMesh PS sales

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APPENDIX 1
Financial model 040704.

Financial model 061404. D'art base case scenario.

APPENDIX 2
Gantt chart: Marketing tools, key activities, Prof Ed, Clinical, internal training

Appendix 3

2005 Forecasts

APPENDIX 4
Pre launch and launch budget

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